



**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of an Exclusive/Co-Exclusive Patent License: Development and Commercialization of Next Generation Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-like tyrosine kinase 3 (FLT3) Expressing Cancers**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive/Co-Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Senti Bio (“Senti”), located in South San Francisco, CA.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive/Co-Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240)-276-7856; Facsimile: (240)-276-5504; E-mail: [jim.knabb@nih.gov](mailto:jim.knabb@nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

E-133-2016: FLT3-Specific Chimeric Antigen Receptors and Methods Using Same

1. US Provisional Patent Application 62/342,394, filed May 27, 2016 (E-133-2016-0-US-01);
2. International Patent Application PCT/US2017/034,691, filed May 26, 2017 (E-133-2016-0-PCT-02)
3. EP Patent Application No.:17729627.4, filed December 11, 2018 (E-133-2016/0-EP-03)
4. US Patent Application No.: 16/304,552, filed November 26, 2018 (E-133-2016/0-US-05)
5. Australia Patent Application No.: 2017271606, filed November 13, 2018 (E-133-2016/0-AU-06)
6. Canadian Patent Application No.: 3025516, filed November 23, 2018 (E-133-2016/0-CA-07)
7. Japan Patent Application No.: 2018-561669, filed November 22, 2018 (E-133-2016/0-JP-08)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive/co-exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to: “the development of a universal/split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, for the prophylaxis or treatment of cancers expressing FMS-like tyrosine kinase 3 (FLT3; also known as CD135), wherein the CAR construct binds to the FLT3-binding domain referenced as NC7 in the invention, but NC7 is not included in the CAR construct. Specifically excluded from the field of use for this exclusive license are FLT3-specific CAR -based immunotherapies wherein the CAR construct comprises the FLT3-binding domain

referenced as NC7 in the invention as well as an intracellular signaling domain.” The proposed territory is worldwide.

A co-exclusive license to: “the development of a multi-specific FLT3 CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.” The proposed territory is worldwide.

A co-exclusive license to: “the development of a FLT3-specific Regulated/Switch/Logic-Gated CAR-based immunotherapy using autologous or allogeneic human lymphocytes (T cells or NK cells) transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.” The proposed territory is worldwide.

This technology discloses a CAR therapy that targets FLT3 by utilizing the anti-FLT3 binder known as NC7. FLT3 (CD135) is a cytokine receptor expressed on hematopoietic progenitor cells and is one of the most frequently mutated genes in acute myeloid leukemia (AML) and infant acute lymphoblastic leukemia (ALL). FLT3 mutation leads to increased cell surface expression and therefore on leukemic cells, which makes it an attractive candidate for cellular therapies such as CAR-T.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive/co-exclusive license will be royalty bearing, and the prospective exclusive/co-exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that

establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: March 28, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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